

### **REMARKS**

In response to the Examiner's comment on page 3 of the Final Rejection regarding the lack of antecedent basis for the main plane and center line of claim 1, and in view of the fact that all dependent claims referencing the main plane and center line have been canceled, claim 1 has been amended to delete the references to the main plane and center line.

Claims 1 and 37 have been amended to clarify that the annular member is still an annular member in the second, expanded position. Basis for this amendment to claims 1 and 37 can be found, for example, at page 8, lines 21-25 of the specification as originally filed.

Claim 37 has also been amended to require that pairs of the staple-like elements are aligned with each other on said annular member. Basis for this amendment can be found on page 8, lines 31-35 of the specification as originally filed.

Claim 50 has been amended to correct a typographical error.

Claims 10, 36 and 58-64 have been canceled without prejudice to resubmission, since these claims were withdrawn from consideration as drawn to a non-elected invention.

New claim 65 has been added. Basis for new claim 65 can be found, for example, in Fig. 1 and the accompanying description.

Upon entry of this amendment, claims 1-9, 37, 40-57 and 65 will be pending.

### **Information Disclosure Statement**

The applicant submitted a Supplemental Information Disclosure Statement ("IDS") on April 21, 2004, in the above-identified application. However, the Examiner did not return the initialed substitute forms PTO-1449 that were enclosed with the April 21, 2004, IDS with the Final Rejection. Thus, the Examiner is requested to return a copy of the initialed substitute forms PTO-1449 to the applicant to indicate that the references in that IDS have been considered.

### **Request to Withdraw the Finality of the Final Rejection**

On October 6, 2004, the applicant filed a Request to Withdraw the Finality of the Rejection. The applicant has not yet received a response to this request. Should the Examiner require a courtesy copy of this request, the Examiner is asked to call applicant's representative and a courtesy copy will be provided.

### **Rejection Under 35 U.S.C. §102(b)**

Claims 1-7, 37, 40-43 and 46-49 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent no. 5,366,462 (Kaster et al.). This rejection, at least insofar as it applies to claims 1-7, 37, 40-43 and 46-49, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

With reference to claims 1 and 37, these claims have been amended to clarify that the annular member is an annular member in both the first, unexpanded position and the second, expanded position. This is an important feature of the invention since the annular member is employed to connect, for example, two blood vessels to join an artery to a bypass graft. It is important that the connector remain an annular member after expansion so that the connection of the blood vessels extends around the entire circumference of the vessels to thereby provide an effective connection that does not leak or have a weak spot due to a gap in the annular member used to make the connection.

In contrast, it can be seen from Figs. 8-10 of Kaster et al. that the staple 12 of Kaster et al. is a flat staple, as shown in Figs. 8-9, that is formed into a circular shape shown in Fig. 10. As a result of this method of manufacture, the connecting unit 46 of the staple 12 of Kaster et al. will always have a gap between the ends of the connecting unit 46, as is clearly shown in Fig. 10 of Kaster et al. It is apparent from this that Kaster et al. does not intend to expand the connecting unit 46 of staple 12, in use, since such expansion could only occur as a result of a widening of the gap in connecting unit 46. The widening of the gap in connecting unit 46 would create a portion of the connection that could leak or create a substantial weakness in the area of the widened gap, since there are no wall engaging members 43, 44 to engage the walls of the vessels in the area of the gap.

In order to clarify this important distinction between the annular member of claims 1 and 37, and the staple 12 of Kaster et al., claims 1 and 37 have been amended to make it clear that the annular member is an annular member both in the first, unexpanded position, and in the second, expanded position. This distinguishes the annular member of claims 1 and 37 from the staple of Kaster et al., since expansion of the staple of Kaster et al. would occur by virtue of a widening of the gap in connecting unit 46, as explained above, thereby resulting in a staple that is no longer annular in shape. The expanded staple of Kaster et al. would not be annular because widening of the gap would result in a substantial discontinuity in the connecting unit 46, such that the connecting unit 46 would no longer be annular. Accordingly, for at least this reason, claims 1 and 37, as amended, are considered to be novel over Kaster et al.

In addition, claim 37 has been amended to require that pairs of staple-like elements are aligned with one another on the annular member, as shown in Fig. 1 of the present application, and in Figures A-C attached hereto. As can be clearly seen from Fig. 10 of Kaster et al., the wall engaging members 43, 44 are offset from one another on the connecting element 46, rather than aligned with one another as in the present application. Thus, for this additional reason, claim 37, as amended, is considered to be novel over Kaster et al.

All of the remaining claims depend from either claim 1 or claim 37 and thus are considered to be novel for at least this reason, as well as additional reasons given below for some of the dependent claims.

Moreover, there is no teaching, suggestion or motivation in Kaster et al. to form the connecting unit 46 from a continuous, expandable annular member that expands to form a larger annular member, in use. As discussed above, this is an important feature of the invention since it provides a more reliable connection of blood vessels by connecting around the entire circumference of the vessel in the expanded condition. Thus, all pending claims are also considered to be unobvious over Kaster et al. for at least this reason.

Accordingly, favorable consideration and withdrawal of the rejection of claims 1-7, 37, 40-43 and 46-49 under 35 U.S.C. §102(b) is requested.

In addition, with respect to claim 5 of the present application, the Examiner has taken the position that the extreme tips of the wall engaging members 44 of Kaster et al. are curved in the starting position (Fig. 10) to approximate the anticipated curve of the tips resulting from the deformation of the wall engaging members 44 to the joining position (Fig. 10). The applicant disagrees with this characterization of the teachings of Kaster et al.

More specifically, it can be seen that the bend in the wall engaging members 44 of Kaster et al. shown in the starting position in Fig. 10, and again in Figs. 14-17 of Kaster et al, is very different from the curved shape of the wall engaging members 44 shown in the joining position of Fig. 19 of Kaster et al. From this it is clear that the bend in the wall engaging members 44 of Kaster et al. in the starting position of Fig. 10, does not approximate the curvature of the wall engaging members 44 of Kaster et al. in the joining position shown in Fig. 19.

Furthermore, it is not the extreme tips of the wall engaging members 44 of Kaster that are bent, but rather, the bend in the Kaster et al. wall-engaging members 44 is located a substantial distance from the extreme tips of the wall engaging members 44, as can be seen in Fig. 10. This is certainly not a curvature of the extreme tips as is claimed in claim 5 of the present application.

Moreover, this feature can be important in the use of the device since, in practice, it can prove to be extremely difficult to obtain consistent, equal deformation of the wall engaging members 44 from the position shown in Fig. 10 of Kaster et al. to the position shown in Fig. 19 of Kaster et al. since this requires both a substantially homogeneous material in the wall engaging members 44 (i.e. no manufacturing defects) and a very precise application of force to consistently deform the wall engaging members 44. As a result, it is to be expected that in many cases, the deformation of different wall engaging members 44 of Kaster et al. will not be consistent due to manufacturing defects or imprecise application of force to the wall engaging members 44.

The present invention, as claimed in claim 5, alleviates this problem by providing the extreme tips of the staple-like elements with a curvature, prior to deformation, that approximates the final, deformed shape to thereby reduce the amount of deformation of these tips required to deform them to the final, deformed shape. In this manner, more consistent shapes of the final, deformed tips of the staple-like elements, can be obtained. In order to facilitate understanding of this feature, the applicant encloses three figures showing a connector in accordance with the present invention having the feature of claim 5, in a first, starting position (Fig. A), a second, intermediate position after expansion of the annular member but prior to final deformation of staple-like elements (Fig. B), and in the final, joining position with the staple-like elements deformed to provide a connection (Fig. C). If the Examiner considers it appropriate, the applicant is willing to add Figs. A-C to the present application by a drawing amendment in order to facilitate a better understanding of the invention.

Accordingly, for these additional reasons, claim 5 is considered to be both novel and unobvious over Kaster et al. Favorable consideration and withdrawal of the rejection of claim 5 under 35 U.S.C. §102(b) over Kaster et al. is requested.

Claims 8-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kaster et al. in view of U.S. Patent no. 5,104,399 (Lazarus). This rejection, at least insofar as it applies to claims 8-9, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

First, the combination of Lazarus with Kaster et al. is inappropriate since the Examiner characterizes Kaster et al. as relating to an expandable connector, whereas Lazarus relates to a connector that contracts to a smaller size, in use. See col. 5, lines 8-10 of Lazarus. As a result, a skilled person would not consider the teachings of Lazarus when desiring to provide an expandable connector.

Second, Lazarus does not teach or suggest a connector having an annular member that is annular both in a first, unexpanded position, and a second, expanded joining position. Rather, in the joining position of Lazarus, the connector is smaller in size than in the first, starting position. See col. 5, lines 8-10 of Lazarus. Accordingly, Lazarus does not cure the defect of Kaster et al. discussed above with respect to the novelty rejection of claims 1 and 37, as amended. Therefore, since neither Lazarus nor Kaster et al. teaches this feature of the claims, as amended, the combination of Lazarus and Kaster et al. fails to make out a *prima facie* case of obviousness against any of the amended claims.

Third, it would not be obvious to modify the connector of Kaster et al. to provide a sinusoidal member in view of Lazarus et al. The Examiner alleges that it would be obvious to modify the connector of Kaster et al. to provide a sinusoidal pattern in view of Lazarus to enhance expandability. However, Kaster et al. does not contemplate expansion of its connector and thus the skilled person has no reason to want to enhance the expandability of the Kaster et al. connector. In addition, Lazarus does not expand its connector, but rather contracts it. See col. 5, lines 8-10 of Lazarus. Thus, the skilled person would not glean from Lazarus that the provision of a sinusoidal pattern would enhance expandability since Lazarus desires the exact opposite, namely, contractibility.

Finally, making the modification as suggested by the Examiner, to place the staple-like elements at the apexes of the connector as shown in Lazarus Figs. 3-4, would render the Kaster et al. device non-functional. Specifically, as can be seen from Figs. 18-19 of Kaster et al., the wall engaging members 43 are necessary to close with the wall engaging members 44 to form the connection. If the design of Lazarus is adopted, there are no more wall engaging members 43 and thus the device of Kaster et al. will no longer be capable of making a suitable connection. In this regard, note that Lazarus requires the use of two separate connectors, e.g. those shown in Figs. 3 and 4, to make a connection.

Accordingly, for at least the foregoing reasons the rejection of claims 8-9 under 35 U.S.C. 103(a) over a combination of Kaster et al. and Lazarus should be withdrawn. Favorable consideration and withdrawal of the rejection are requested.

Claims 44-45 and 50-57 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaster et al. This rejection, at least insofar as it applies to claims 44-45 and 50-57, as amended, is respectfully traversed and reconsideration is requested for the reasons which follow.

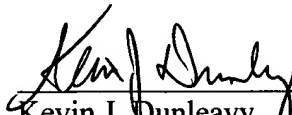
Specifically, the same reasoning given above with respect to claim 1 also applies here since each of these claims depends from claim 1. In addition, several features of these claims are missing from Kaster et al., as the Examiner admits. As a result, Kaster et al., taken alone, does not make out a case of *prima facie* obviousness against certain of these claims, since features of these claims are completely missing from the reference, e.g. tapering to form a B-shape. Accordingly, the Examiner is requested to withdraw this rejection or provide evidence substantiating that tapering to form a B-shape is obvious to a skilled person. Favorable consideration and withdrawal of the rejection is requested.

Finally, new claim 65 requires that each staple portion is tapered from a position proximate the annular member. Kaster et al. does not show this feature since the tapering of the wall engaging members 43, 44 of Kaster et al. does not begin at a position proximate the annular member. This feature is significant in that the tapering of the staple portion is employed to provide a more consistent deformation of the staple portions in use. Accordingly, new claim 65 is considered to be separately patentable over Kaster et al. for this additional reason.

Favorable consideration, entry of this amendment and issuance of a notice of allowance are requested.

Respectfully submitted,

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